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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,768	03/26/2004	William F. Niland	HQS-107US	9079

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3993	

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,768	NILAND ET AL.	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-18 and 20-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-18 and 20-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/24/2006 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 16,20-26,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua ('744) in view of Aylsworth et al. ('490) and Ko et al.('527).

As to claim 16, Chua (fig.2) discloses a system for delivering humidified gas to a patient, said system comprising: a supply unit (10) configured to deliver humidified gas; and a delivery tube assembly (30) having a delivery tube with a proximal end (at #60) and a distal end (at #52), said delivery tube assembly also having a fitting (60) positioned at said proximal end of said delivery tube and adapted for connection to said supply unit, said delivery tube assembly being configured (42) to transfer heat to the humidified gas received from said supply unit.

The difference between Chua and claim 16 is a nasal cannula releasably coupled to the distal end of said delivery tube to receive humidified gas from the delivery tube of the delivery tube assembly.

Aylsworth et al.(col.3, lines 63-65), in a system for delivering humidified gas to a patient, teach a nasal cannula coupled to the distal end of the delivery tube to receive humidified gas from said distal end of said delivery tube of said delivery tube assembly, the nasal cannula also including other patient connected devices including an oxygen mask. Implicit in the combination of a nasal cannula with a mask are the advantages of ensuring a secure and covered patient connection via a mask and providing humidified gas directly into a patient's respiratory passages via a nasal cannula.

It would have been obvious to modify the respiratory mouthpiece or the like (col.3, line 12) of Chua to substitute a mask and nasal cannula because it would have provided the advantages of ensuring a secure and covered patient connection via a mask and providing humidified gas directly into a patient's respiratory passages via a nasal cannula as taught by Aylsworth et al..

To the extent, if any, that the nasal cannula of Aylsworth et al. may not be releasably coupled, resort is had to Ko et al. (col.10, lines 29-31) which teach releasably coupling a nasal cannula (148) or an endotracheal tube to a connector member (146) of a gas delivery tube for the purpose of providing a means for releasably connecting a plurality of different patient interfaces to a gas delivery conduit.

It would have been obvious to releasably couple a nasal cannula to the distal end of the gas supply tube of Chua because it would have provided a means for releasably

connecting a plurality of different patient interfaces to a gas delivery conduit as taught by Ko et al..

As to claim 20, Chua as modified by Aylsworth et al. and Ko et al. disclose a releasable coupling (#54 and col.3, lines 1-12 of Chua and #146 of Ko et al.) configured to couple said nasal cannula to said delivery tube assembly.

As to claim 21, said releasable coupling (54 of Chua) comprises an adapter (52).

As to claim 22, Chua discloses the fitting (60) of said delivery tube assembly (30) is configured for releasable connection (col.3, lines 18-20) to said supply unit (10).

As to claim 23, Chua (fig.1) discloses said supply unit (10) as having a gas inlet (e.g. see inlet on top of supply unit connected to conduit #7) configured to receive gas.

As to claim 24, Chua discloses means (7) for receiving gas from a source (5) of gas and for delivering the gas to said gas inlet of said supply unit.

As to claim 25, Chua discloses said gas receiving means comprising a tube (7).

As to claim 26, Chua discloses said gas receiving means (7) further comprises a fitting (see connection to ventilator 5 in fig.1) configured for connection to the source of gas.

Claim 32 is substantially equivalent in scope to claim 16 and is included in Chua as modified by Aylsworth et al. and Ko et al. for the reasons set forth above with respect to claim 16.

4. Claims 17,18,27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua ('744) in view of Aylsworth et al. ('490) and Ko et al.('527) as applied to claims 16,20-26,32 above, and further in view of McComb ('946).

The difference between Chua and claim 17 is said supply unit being configured to deliver humidified gas at a flow rate of about 1 liter per minute to about 8 liters per minute.

McComb, in a system for delivering humidified gas to a patient, teaches a supply unit being configured to deliver humidified gas at flow rates between 2 to 150 liters/minute which includes a flow rate of about 1 liter per minute to about 8 liters per minute for the purpose of accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit (col.5, lines 48-61).

While Chua is silent as to a particular flow rate or range of flow rates, it would have been obvious to modify Chua to provide a wide range of flow rates including 1-8 liters per minute because it would have provided a means for accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit as taught by McComb.

As to claim 18, McComb as discussed above with respect to claim 17 teaches the delivery of humidified gas at flow rates between 2 to 150 liters/minute which includes a flow rates above about 20 liters per minute.

As to claims 27-29, McComb teaches a liquid inlet (e.g.60) configured to receive supplemental liquid from water reservoir (26).

Claim 30 is substantially equivalent in scope to claim 17 and is included in Chua as modified by McComb for the reasons set forth above with respect to claim 17.

5. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chua ('744) in view of McComb ('946) and Aylsworth et al. ('490).

The differences between Chua and claim 31 are the delivery of humidified gas at a flow rate of about 1 liter per minute to about 8 liters per minute and a nasal cannula configured to be coupled to receive humidified gas from said distal end of said delivery tube of said delivery tube assembly.

McComb, in a system for delivering humidified gas to a patient, teaches a supply unit being configured to deliver humidified gas at flow rates between 2 to 150 liters/minute which includes a flow rate of about 1 liter per minute to about 8 liters per minute for the purpose of accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit (col.5, lines 48-61).

While Chua is silent as to a particular flow rate or range of flow rates, it would have been obvious to modify Chua to provide a wide range of flow rates including 1-8 liters per minute because it would have provided a means for accommodating patient's having differing respiratory capacities and for accommodating a ventilator alone or a ventilator in combination with an anesthesia circuit as taught by McComb.

Aylsworth et al.(col.3, lines 63-65), in a system for delivering humidified gas to a patient, teach a nasal cannula configured to be coupled to receive humidified gas from said distal end of said delivery tube of said delivery tube assembly, the nasal cannula also including other patient connected devices including an oxygen mask. Implicit in the combination of a nasal cannula with a mask are the advantages of ensuring a secure

and covered patient connection via a mask and providing humidified gas directly into a patient's respiratory passages via a nasal cannula.

It would have been obvious to modify the respiratory mouthpiece or the like (col.3, line 12) of Chua to substitute a mask and nasal cannula because it would have provided the advantages of ensuring a secure and covered patient connection via a mask and providing humidified gas directly into a patient's respiratory passages via a nasal cannula as taught by Aylsworth et al..

Claim 33 is substantially equivalent in scope to claim 31 and is included in Chua as modified by Aylsworth et al. for the reasons set forth above with respect to claim 31.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 34-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackmer (WO 86/02276).

As to claim 34, Blackmer (fig.1) discloses a system for delivering humidified gas to a patient, the system comprising: a supply unit (1) configured to deliver breathing gas; and a delivery tube (2) releasably coupled to the supply unit, the delivery tube being configured to transfer heat (24,25) to the breathing gas received from the supply unit, wherein the breathing gas is humidified by fluid (10) that has flowed through the delivery tube.

As to claim 35, Blackmer (fig.1) discloses the supply unit (1) provides fluid (10) for humidifying the breathing gas.

As to claim 36, Blackmer discloses the fluid flow through the system is configured such that the fluid heats the breathing gas prior to humidifying the breathing gas (page 9, lines 10-24 discloses hydrophilic membranes with allow small amounts of water vapor to humidify breathable gas while heat radiates to breathable gas to warm it; the structure of the membranes is such that heat from radiation would pass through the membranes at a greater rate than liquid water vapor).

As to claim 37, Blackmer discloses a nasal cannula (51) coupled to the delivery tube.

As to claim 38, Blackmer discloses the nasal cannula is releasably coupled to the delivery tube (page 11, lines 6-8 discloses nasal cannula being disposable, thus releasably coupled).

As to claim 39, Blackmer (fig.1) discloses a warming and humidifying system for a breathing gas comprising: a fluid supply (10); a means (2) for heating the breathing gas with fluid from the fluid supply; and a means (#2 and page 9, lines 10-24) for humidifying the breathing gas with the fluid after the fluid has heated the breathing gas (page 9, lines 10-24 discloses hydrophilic membranes with allow small amounts of water vapor to humidify breathable gas while heat radiates to breathable gas to warm it; the structure of the membranes is such that heat from radiation would pass through the membranes at a greater rate than liquid water vapor).

As to claim 40, Blackmer (fig.1) discloses a method for delivering breathing gas to a patient, the method comprising the steps of: coupling a delivery tube (2) to a supply unit

(1); coupling a nasal cannula (51) to the delivery tube; delivering breathing gas (3) from the supply unit to the delivery tube; heating (24,25) the breathing gas with a fluid in the delivery tube (page 9, lines 10-24); humidifying the breathing gas (page 9, lines 10-24); and delivering the breathing gas from the delivery tube to (via #4) the nasal cannula for delivery to the patient.

As to claim 41, Blackmer discloses the step of using the fluid to humidify the breathing gas after the fluid heats the breathing gas (page 9, lines 10-24 discloses hydrophilic membranes with allow small amounts of water vapor to humidify breathable gas while heat radiates to breathable gas to warm it; the structure of the membranes is such that heat from radiation would pass through the membranes at a greater rate than liquid water vapor).

As to claim 42, Blackmer (fig.1) discloses a method of delivering a breathing gas to a patient, the method comprising the steps of: coupling a delivery tube (2) to a supply unit (1); coupling a nasal cannula (51) to the delivery tube; delivering breathing gas from the supply unit to (via #3) the delivery tube such that the breathing gas flows in a first direction through the delivery tube (inlet #3, outlet #4); heating (24,25) the breathing gas with a fluid in the delivery tube such that the fluid flows in at least the first direction through the delivery tube; and delivering the breathing gas from the delivery tube to (via outlet #4) the nasal cannula for delivery to the patient.

As to claim 43, Blackmer discloses the step of humidifying the breathing gas with the fluid (page 9, lines 10-24).

As to claim 44, Blackmer discloses humidifying the gas with the fluid is performed after the fluid heats the breathing gas (page 9, lines 10-24 discloses hydrophilic membranes with allow small amounts of water vapor to humidify breathable gas while heat radiates to breathable gas to warm it; the structure of the membranes is such that heat from radiation would pass through the membranes at a greater rate than liquid water vapor).

As to claim 45, Blackmer discloses flowing the fluid in a second direction (water flows into inlet 5 which is adjacent gas outlet 4), opposite the first direction, through the delivery tube.

Response to Arguments

8. Applicant's arguments with respect to claims 16-18,20-45 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron J. Lewis
AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
October 01, 2006